UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

CREAGRI, INC., a California Corporation, Plaintiff, v. PINNACLIFE, INC., a Nevada Corporation, Defendant.	Case No.: 11-CV-6635-LHK ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OF INVALIDITY

Plaintiff CreAgri, Inc. ("CreAgri") brings this action against Defendant Pinnaclife, Inc. ("Pinnaclife") for infringement of U.S. Patent No. 6,416,808 (filed Aug. 31, 2001) ("the '808 Patent") and U.S. Patent No. 8,216,599 (filed Feb. 13, 2003) ("the '599 Patent"). *See* Second. Am. Compl., ECF No. 50. Before the Court are Pinnaclife's Motions for Summary Judgment of Invalidity, ECF No. 103 ("Def. MSJ"), and Noninfringement,[1] and CreAgri's Motion for Summary Judgment of Infringement, ECF. No. 106 ("Pl. MSJ"). Having reviewed the parties' submissions, the record in this case, and the relevant law, the Court GRANTS Pinnaclife's Motion for Summary Judgment of Invalidity. The Court concludes that all claims of the '808 Patent are invalid as anticipated under 35 U.S.C. § 102 and that all claims of the '599 Patent are invalid for failure to

[1] Although Pinnaclife moved for summary judgment of invalidity only and CreAgri moved for summary judgment of infringement only, Pinnaclife, *see* ECF No. 155 at 4, moved for summary judgment of noninfringement as part of its opposition to CreAgri's motion for summary judgment, *see* ECF No. 113-1 ("Pl. Opp.").

meet the written description, enablement, and utility requirements of 35 U.S.C. §§ 101 and 112(a). Because the Court concludes that all claims of the patents-in-suit are invalid, the Court does not reach the issues raised in CreAgri's Motion for Summary Judgment of Infringement or Pinnaclife's Motion for Summary Judgment of Noninfringement.

I. BACKGROUND

A. Factual Background

CreAgri and Pinnaclife both sell products, including dietary supplements, containing olive-derived phenolic compounds intended to promote health. Pl. Opp. at 2.[2] Olives naturally contain the phenolic compounds oleuropein, hydroxytyrosol, and tyrosol. '808 Patent 2:9–30. Olive oil is a principal fat component of the Mediterranean diet, which has been linked to a lower incidence of certain ailments, such as coronary heart disease and some cancers. *Id.* 2:9–14. Massive amounts of "waste water" or "vegetation water" are produced as a byproduct of olive oil production. Discarding this water creates a significant economic burden for olive oil mills. *See* Francesco Visioli, et al., 47 *Antioxidant and Other Biological Activities of Olive Mill Waste Waters*, J. Agric. Food Chem., 3397–3401 (1999), *available at* Marshall Decl. Ex. D, ECF No. 103-2. Because of the known health benefits of olives and olive extracts, efforts have been made to leverage olive mill vegetation water for therapeutic uses, rather than simply discarding it as waste. CreAgri has secured, and now asserts, two patents over certain compositions of phenols derived from this waste water and uses thereof. '808 Patent; '599 Patent.

The '808 Patent, entitled "Method of Obtaining a Hydroxytyrosol-Rich Composition from Vegetation Water," claims, despite its title, *compositions* of olive-derived dietary supplements containing hydroxytyrosol and oleuropein or hydroxytyrosol and tyrosol at certain weight ratios. *See* '808 Patent at 3:43–51. The '808 Patent contains two independent claims and four dependent claims, all of which CreAgri asserts in this case. Independent claim 1 recites a range of hydroxytyrosol-to-oleoeuropein weight ratios and reads as follows:

> A dietary supplement comprising an aqueous extract of olives containing a weight ratio of hydroxytyrosol to oleoeuropein of between about 5:1 and about 200:1.

[2] Phenolic compounds are compounds with one or more phenyl ($-C_6H_5OH$) groups. Def. MSJ at 2. A compound with more than one phenyl group is a polyphenol.

Claims 2 through 4 depend from claim 1. Claim 2 recites a narrower range of hydroxytyrosol-to-oleoeuropein weight ratios. Claim 3 recites a dried supplement in powder form, and claim 4 recites an extract "in the form of a tablet, capsule, pill, or confection food additive." Independent claim 5 is similar to claim 1 except that it recites a range of hydroxytyrosol-to-tyrosol weight ratios:

> A dietary supplement comprising an aqueous extract of olives containing a weight ratio of hydroxytyrosol to tyrosol of between about 3:1 and about 50:1.

Dependent claim 6 recites a narrower range of hydroxytyrosol-to-tyrosol weight ratios. CreAgri filed the '808 Patent on August 31, 2001, and the Patent issued on July 9, 2002. *Id.*

The '599 Patent, entitled "Method for Treatment of Inflammation," relates to using olive plant extracts to "treat[] AIDS-associated neurological disorders, inflammation and inflammation-associated disorders." '599 Patent 1:10–14 ("Field of the Invention"). The claims recite methods for treating specified inflammatory conditions with various mixtures of hydroxytyrosol or hydroxytyrosol and oleuropein. *See* '599 Patent. The '599 Patent contains two independent claims and fourteen dependent claims. The first independent claim, claim 1, reads as follows:

> A method of treating a subject having an inflammatory condition characterized by a detectable clinical symptom or change in a level of a biochemical marker with respect to the normal range of the marker, the method comprising:
>
> administering to the subject a dose corresponding to between about 0.1 mg/kg body weight and 2000 mg/kg body weight daily of a first treatment agent comprised of an olive plant extract having a weight ratio of hydroxytyrosol to oleuropein of between about 1:1 and about 200:1; and
>
> continuing said administration until there is observed a return of the marker level to the normal range or a desired change in the clinical symptom,
>
> where the marker or the clinical symptom is selected from the group consisting of
>
> (i) elevated levels of C-reactive protein in the case of coronary inflammation;
>
> (ii) respiratory distress in the case of bronchial inflammation; and
>
> (iii) elevated CSF levels of isoprostanes or clinical symptoms determined from neuropsychological testing in the case of neuro inflammation.

All fourteen of the dependent claims depend from claim 1. The other independent claim, claim 16, uses a slightly different therapy—substantially purified hydroxytyrosol and oleuropein—to treat a broader set of conditions:

> A method of treating an inflammatory condition in a subject in need of such treatment, comprising administering to said subject a dosage amount corresponding to between about 0.1 mg/kg body weight and 2000 mg/kg body weight daily of substantially purified hydroxytyrosol or a substantially purified mixture of hydroxytyrosol and oleuropein, wherein said inflammatory condition is in response to a condition selected from the group

consisting of: delayed type hypersensitivity reaction, psoriasis, an autoimmune disease, organ transplant, pain, fever, and tissue graft rejection.

CreAgri filed the '599 Patent on February 13, 2003, and, following a long prosecution history, the Patent issued on July 10, 2012. '599 Patent.

B. Procedural Background

CreAgri filed its Complaint on December 23, 2011, alleging that Pinnaclife's olive-derived supplements infringe the '808 Patent. ECF No. 1. Following a first amendment and a successful Motion to Dismiss some of CreAgri's claims, *see* ECF Nos. 27, 46, CreAgri filed its operative complaint on January 1, 2013, alleging infringements of both the '808 and '599 Patents. *See* ECF No. 50. In its answer, Pinnaclife included counterclaims seeking declaratory judgments of invalidity and noninfringement of the '808 and '599 Patents, as well as a declaratory judgment that the '808 Patent was unenforceable due to inequitable conduct. *See* ECF No. 55. The Court issued an order construing the disputed claims of the Patents on April 16, 2013. ECF No. 67 ("Claim Construction Order"). Pinnaclife now moves for summary judgment on invalidity and noninfringement and CreAgri moves for summary judgment of infringement.

II. LEGAL STANDARD

A. Summary Judgment

Summary judgment is appropriate if, viewing the evidence and drawing all reasonable inferences in the light most favorable to the nonmoving party, there are no genuine disputed issues of material fact, and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). At the summary judgment stage, the Court "does not assess credibility or weigh the evidence, but simply determines whether there is a genuine factual issue for trial." *House v. Bell*, 547 U.S. 518, 559–60 (2006). A fact is "material" if it "might affect the outcome of the suit under the governing law," and a dispute as to a material fact is "genuine" if there is sufficient evidence for a reasonable trier of fact to decide in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Mere conclusory, speculative testimony in affidavits and moving papers is insufficient to raise genuine issues of fact and defeat summary judgment. *See Thornhill Publ'g Co. v. GTE Corp.*, 594 F.2d 730, 738 (9th Cir. 1979).

The moving party bears the initial burden of identifying those portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. *Celotex Corp.*, 477 U.S. at 323. Where the moving party will have the burden of proof on an issue at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party, but on an issue for which the opposing party will have the burden of proof at trial, the party moving for summary judgment need only point out "that there is an absence of evidence to support the nonmoving party's case." *Id.* at 325; *accord Soremekun v. Thrifty Payless, Inc.*, 509 F.3d 978, 984 (9th Cir. 2007). Once the moving party meets its initial burden, the nonmoving party must set forth, by affidavit or as otherwise provided in Rule 56, "specific facts showing that there is a genuine issue for trial." *Liberty Lobby*, 477 U.S. at 250 (internal quotation marks omitted). If the nonmoving party's "evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249–50 (internal citations omitted).

B. Invalidity

Patents are presumed to be valid. 35 U.S.C. § 282(a). A party challenging the validity of a patent bears the burden of proving invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011). The parties dispute the effect of various PTO proceedings on the applicable standard of proof. However, as explained in more detail below, nothing about the initial PTO examination of the patents-in-suit or certain reexamination proceedings regarding the '808 Patent changes the presumption of validity in this case. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2250 (2011) ("Nothing in § 282's text suggests that Congress meant to depart from that understanding to enact a standard of proof that would rise and fall with the facts of each case.").

III. THE '808 PATENT

Pinnaclife contends that all claims of the '808 Patent are invalid as anticipated under 35 U.S.C. § 102 or obvious under 35 U.S.C. § 103. In particular, Pinnaclife directs the Court to U.S. Patent No. 6,358,542 ("Cuomo") and an article entitled "Polyphenolic Content in Five Tuscany Cultaivars of *Olea europaea* L." ("Romani") as invalidating prior art. The Court finds that all

claims of the '808 Patent are invalid as anticipated by Cuomo, Romani, or both, and therefore the Court GRANTS Pinnaclife's Motion for Summary Judgment of Invalidity as to the '808 Patent.

A patent claim is invalid for anticipation if, among other reasons, "the invention was . . . described in a printed publication in this or a foreign country . . . , more than one year prior to the date of the application for patent in the United States," 35 U.S.C. § 102(b) (2006), or "the invention was described in . . . a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent," *id.* § 102(e) (2006).[3] A claim is anticipated under § 102, and thus invalid, "if each and every limitation is found either expressly or inherently in a single prior art reference." *Bristol–Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1374 (Fed. Cir. 2001) (internal quotation marks and citation omitted); *accord Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006). Put simply, "[t]hat which infringes, if later, would anticipate, if earlier." *Peters v. Active Mfg.*, 129 U.S. 530, 537 (1889) (internal quotation mark omitted).

Anticipation under § 102 is a two-step inquiry. *See Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 933 (Fed. Cir. 2003). The first step is claim construction. *Id.*; *see Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("'claim must be construed before determining its validity just as it is first construed before deciding infringement.'" (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 996 n.7 (Fed. Cir. 1995) (Mayer, J., concurring), *aff'd*, 517 U.S. 370 (1996)). The second step is a comparison of the properly construed claim to the prior art. *Medichem*, 353 F.3d at 933.

The Court previously construed the claims in its claim construction order. *See* ECF No. 67 at 40. As relevant here, the Court construed the following terms of the '808 Patent:

[3] On September 16, 2011, the America Invents Act was enacted into law. *See* Pub. L. 112-29, 125 Stat. 285 ("AIA"). The AIA fundamentally changes the rules of invalidity under 35 U.S.C. § 102. *See id.* at § 3(b)(1). The application for the '808 Patent, however, was filed before the effective date of the AIA, and therefore the prior version of § 102 applies. *See id.* at § 3(n).

Claim Language	Construction
"comprising" or "comprised of"	"including but not limited to"
the preamble "a dietary supplement" in Claims 1 and 5 of the '808 Patent	the preamble "a dietary supplement" in Claims 1 and 5 of the '808 Patent is not a claim limitation.
weight ratios claimed in the '808 Patent	the claimed weight ratios in Claims 1 and 5 of the '808 Patent apply to the "aqueous extract of olives," not to the "dietary supplement."
"aqueous extract of olives"	"an aqueous solution containing a water-soluble preparation from an olive plant," with no restriction on the process by which the "aqueous solution" is obtained.

A. Significance of the PTO Final Office Action

The '808 Patent is currently under reexamination before the PTO in *Ex Parte* Reexamination of U.S. Patent No. 6,416,808. As part of that reexamination, and after the summary judgment briefing in this case concluded, the PTO rejected all the claims of the '808 Patent in a Final Office Action. *See* ECF No. 140. The PTO examiner found claims 1-5 anticipated by Cuomo and claim 6 obvious in light of Cuomo. *Id*. The examiner further concluded that claims 1 and 4-6 were anticipated by Romani; that claim 2 was obvious in light of Romani; and that claims 3 and 4 were obvious in light of Romani in view of Cuomo. *Id*. Cuomo and Romani are the same prior art references that Pinnaclife has asserted against the '808 Patent in this case. In their briefs, the parties debate the significance of an earlier non-final action in the same reexamination as it pertains to the present motion. This debate applies to the recently issued Final Office Action as well. For the following reasons, the Court determines that neither the Final Office Action nor the non-final action is due deference, and thus the Court conducts an independent review of the parties' invalidity arguments.

As stated above, a patent is presumed valid in litigation. 35 U.S.C. § 282. In a reexamination, however, there is no such presumption. *In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008). The difference in standard of proof significantly reduces the relevance of the PTO's conclusions. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1428 (Fed. Cir. 1988) ("The two forums

take different approaches in determining invalidity and on the same evidence could quite correctly come to different conclusions."). At least one other court has found that "the examiners' conclusions on reexamination are not relevant to the merits" of a summary judgment motion. *Sigram Schindler Beteiligungsgesellschaft mbH v. Cisco Sys., Inc.*, 726 F. Supp. 2d 396, 415 (D. Del. 2010). Another court has struck evidence of reexamination proceedings from consideration at summary judgment, and the Federal Circuit has ruled that such evidence should be kept from a jury. *Tesco Corp. v. Weatherford Int'l Inc.*, 750 F. Supp. 2d 780, 793–94 (S.D. Tex. 2010) (granting a motion to strike evidence of reexamination proceedings with respect to invalidity); *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1343 (Fed. Cir. 2009).

Moreover, although the PTO office action is final, CreAgri still may file a response to the examiner that may result in the PTO's withdrawal of its invalidity conclusion. *See* 37 C.F.R. § 1.116. CreAgri also may appeal the PTO's decision to the Patent Trial and Appeal Board ("PTAB"), *see* 35 U.S.C. § 134(b), and, from there, may appeal any adverse PTAB decision to the Federal Circuit, *see* 35 U.S.C. § 141. The PTO will issue a certification canceling any claims of the '808 Patent determined to be unpatentable only after the time for appeal has expired or any appeal proceeding has terminated. *See* 35 U.S.C. § 307(a). Thus, the PTO's conclusions are "final" in name only; the PTO's adverse decisions are still subject to substantial review. Therefore, the Court reviews Pinnaclife's invalidity contentions without regard to the PTO's office actions.

B. Anticipation by Cuomo

Pinnaclife contends that Cuomo anticipates claims 1-5 of the '808 Patent. *See* Def. MSJ at 9–12. Claims 1, 2, and 5 of the '808 Patent all claim a dietary supplement by way of two limitations: (1) an "aqueous extract of olives," with (2) a weight ratio range of either hydroxytyrosol to oleoeuropein (claims 1 and 2) or hydroxytyrosol to tyrosol (claim 5). Claims 3 and 4, which depend from claim 1, each recite an additional limitation concerning the supplement form. Claim 3 requires a supplement that is "dried to provide a powder extract," and claim 4 recites a supplement that contains an extract "in the form of a tablet, capsule, pill, or confection food product." *Id.*

CreAgri does not contest that Cuomo discloses the weight ratio ranges in claims 1-5 of the '808 Patent,[4] nor does it contest that Cuomo discloses the additional limitations on supplement forms in claims 3 and 4.[5] As shown in the chart below, the parties' only dispute over whether Cuomo anticipates claims 1-5 of the '808 Patent centers on whether Cuomo discloses an "aqueous extract of olives."

Claim	Limitation	Parties' Positions
All	"an aqueous extract of olives"	*Disputed*
1, 3, 4	"containing a weight ratio of hydroxytyrosol to oleoeuropein of between about 5:1 and about 200:1."	Disclosed by Cuomo
2	"a weight ratio of hydroxytyrosol to oleoeuropein of between about 10:1 and about 100:1."	
3	"supplement is dried to provide a powder extract."	
4	"extract is in the form of a tablet, capsule, pill, or confection food additive."	
5	"containing a weight ratio of hydroxytyrosol to tyrosol of between about 3:1 and about 50:1."	

The Court is persuaded that no reasonable jury could conclude that Cuomo fails to clearly and convincingly disclose an "aqueous extract of olives." Accordingly, Pinnaclife is entitled to summary judgment that claims 1-5 of the '808 Patent are invalid as anticipated by Cuomo. Cuomo, which was filed prior to the filing date of the '808 Patent, discloses several "methods of extracting anti-oxidant compositions from olives and the by-products of olive oil production." Cuomo, at 1:8–10. Using several examples, Cuomo provides information about various compositions extracted by way of the disclosed methods. Example 4 of Cuomo describes a method for obtaining a solid antioxidant composition from an olive pulp. The procedure calls for washing the pulp with water (a polar aqueous solvent) to obtain a mixture containing the antioxidants, washing with methanol (a

[4] Table 2 of Cuomo sets forth the percentage—by weight—of hydroxytyrosol, tyrosol, and oleuropein found in what the Court ultimately determines is an "aqueous extract of olives." Cuomo, at 14:38–52.

[5] Cuomo teaches using the extracted compositions in a nutritional supplement "in any convenient form, such as a powder, a tablet or a capsule." Cuomo, at 8:63–9:8.

polar organic solvent), freezing the resulting organic solution, and evaporating the methanol, leaving a solid antioxidant composition. *Id.*, 10:63–11:6. At this point, the solid antioxidant composition is not "an aqueous extract of olives" as that term was construed by the court because it is dry.[6] But Example 11 then describes taking the antioxidant composition from Example 4, dissolving it in 80% aqueous methanol, treating it with hydrochloric acid, and analyzing the acid-treated extract for antioxidant activity and phenolic content using a variety of techniques. *Id.*, 14:13–20.

The Court concludes that Example 11's description of an 80% *aqueous* methanol solution comprising the dissolved olive pulp from Example 4 plainly describes an "aqueous solution containing a water-soluble preparation from an olive plant," and therefore no reasonable jury could conclude that the reference fails to disclose the "aqueous extract of olives" limitations of claims 1 through 5 of the '808 Patent.

In contending otherwise, CreAgri argues that a liquid extract that includes methanol, such as that disclosed in Example 11, cannot be an aqueous extract, even if that extract also includes water. *See* Pl. Opp. at 6 ("[T]he '808 Patent claims are [sic] directed towards 'aqueous extracts' are not meant to encompass 'aqueous-alcoholic extracts' of the type that are discussed in Cuomo."). The Court disagrees.

At the outset, CreAgri's argument is a new and untimely claim construction argument. CreAgri now essentially asserts that the scope of "aqueous extract" is limited to pure water extracts and therefore excludes aqueous-alcoholic extracts such as the 80% aqueous methanol extract of Cuomo's Example 11. But the Court held that an "aqueous extract of olives" is "an aqueous solution containing a water-soluble preparation from an olive plant," not, as CreAgri contends, that an "aqueous extract" is pure water. Neither party asked for a construction of "aqueous extract" that would exclude "aqueous-alcoholic" extracts. In fact, CreAgri proposed a broad construction of "aqueous extract of olives" and in doing so relied on a broad dictionary definition of "aqueous" that itself suggests "aqueous-alcoholic" extracts are merely a subset of "aqueous" extracts. *See*

[6] During claim construction, CreAgri unsuccessfully sought a construction of "aqueous extract of olives" that would have included a powdered extract, so long as it was derived from water. *See* ECF No. 67 at 24.

ECF No. 47 at 10 (relying on "the McGraw-Hill Dictionary of Scientific and Technical Terms" which "defines the word aqueous as something that is 'relating to' water."). For its part, Pinnaclife initially proposed a construction of "aqueous extract of olives" that would have resolved this issue in CreAgri's favor, contending in the parties' Joint Claim Construction Chart that "[a]s used in the '808 patent, an 'aqueous extract' is *not* an 'aqueous-alcoholic extract.'" ECF No. 43 at 3 (emphasis added). Yet Pinnaclife, possibly realizing the impact on anticipation, withdrew this proposal, *see* ECF No. 49 at 14 n.3, with no objection from CreAgri. CreAgri's attempt to relitigate the construction of "aqueous extract" at the summary judgment stage must be rejected.

Moreover, CreAgri's new claim construction argument fails on the merits. The specification of the '808 Patent makes clear that the invention includes—rather than excludes—the use of aqueous-alcoholic extracts. The following passage is key:

> The hydroxytyrosol obtained by the method *of the invention* can be administered orally or parenterally. Oral dosage forms can be in a solid or liquid form. Such dosage forms can be formulated from purified hydroxytyrosol or *they can be formulated from aqueous or aqueous-alcoholic extracts*. Regarding the latter, aqueous or aqueous-alcoholic (e.g., water-methanol or water-ethanol) extracts can be spray-dried to provide a dry powder that can be formulated into oral dosage forms with other pharmaceutically acceptable carriers. *The aqueous or aqueous-alcoholic extracts* can be formulated to contain various weight ratios of hydroxytyrosol to oleoeuropein of between 5:1 and 200:1, preferably between about 10:1 and about 100:1. *The extracts* may also be formulated to contain various weight ratios of hydroxytysol and tyrosol of between about 3:1 and about 50:1, preferably between about 5:1 and about 30:1.

'808 Patent at 7:41–56 (emphases added). In so describing the oral dosage forms "of the invention," this passage explains that forms can be "formulated from aqueous or aqueous-alcoholic extracts." '808 Patent at 7:44–45. The passage then discloses that the aqueous or aqueous-alcoholic extracts can contain the exact weight ratios claimed in the patent.

This passage provides strong evidence of the scope of the claims. More than merely a preferred embodiment, this passage describes "the invention" as a whole. *See, e.g.*, *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1353–54 (Fed. Cir. 2010) (concluding that specification's "reference to 'the present invention' strongly suggests" that the claim carries the same meaning).

Thus, the "strong presumption against a claim construction that excludes a disclosed embodiment," *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1324 (Fed. Cir. 2011), applies here with even more force. Because the patentee described the invention as being formulated from aqueous-alcoholic extracts, this Court refuses to exclude aqueous-alcoholic extracts from the scope of the "aqueous extract" claim language.

CreAgri contends that this passage favors its interpretation. According to CreAgri, because the passage lists "aqueous or aqueous-alcoholic extracts," in the disjunctive, an aqueous extract must be different than an aqueous-alcoholic extract. The Court concludes that the specification's passing use of the disjunctive to connect overlapping adjectives is ambiguous at best. That ambiguity is insufficient to exclude aqueous-alcoholic extracts from the scope of the invention when the specification expressly states that aqueous-alcoholic extracts are included. Indeed, to adopt CreAgri's reading would be to improperly import a purported limitation—that an "aqueous extract" excludes an "aqueous-alcoholic extract"—from the specification into the claims. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc). Accordingly, to avoid any doubt, the Court holds that its construction of "aqueous extract of olives" encompasses "aqueous-alcoholic extracts."

CreAgri makes a half-hearted argument that Cuomo still fails to disclose the claimed "aqueous extract of olives," even under a construction of an "aqueous extract of olives" that includes "aqueous-alcoholic extracts." CreAgri relies on a declaration from its expert, Dr. Bruce German, to contend that an extract that includes methanol, such as that disclosed in Example 11, cannot be an aqueous extract. *See* ECF No. 118-4 at 32–33 ¶ 65 ("German Decl."). But Dr. German fails even to acknowledge that Example 11 expressly analyzes an *aqueous* methanol solution for phenolic content. Instead, Dr. German focuses on Cuomo's Example 4, in which the phenols are first contained in a pure methanol solution. Dr. German neglects to mention that in Example 11 those phenols are dissolved in an aqueous methanol solution, a solution that Cuomo elsewhere expressly describes as a "polar *aqueous* solvent." 6:50–52; *see id.* ("Most preferably, the polar aqueous solvent is a mixture of water and methanol . . . ."). Neither CreAgri nor its expert can create an issue of fact by ignoring the most pertinent disclosure in the asserted prior art. On this

record, no reasonable jury could conclude that Example 11 fails to disclose an "aqueous extract of olives" as the Court has construed the term.

Because CreAgri has failed to show that a genuine issue of fact exists as to whether Cuomo discloses the claimed "aqueous extract of olives," and because Cuomo by clear and convincing evidence discloses all other limitations in claims 1-5 of the '808 Patent, the Court concludes that Pinnaclife is entitled to summary judgment of anticipation as to those claims.[7]

C. Anticipation by Romani

Pinnaclife separately contends that Romani anticipates claims 1, 2, 5, and 6 of the '808 Patent. Def. MSJ at 13–15. Similar to claims 1, 2, and 5—discussed above with respect to Cuomo—dependent claim 6 (together with its independent claim) covers a dietary supplement comprising (1) an aqueous extract of olives with (2) a weight ratio of hydroxytyrosol and tyrosol of between about 3:1 and about 30:1. As with Cuomo, the parties' dispute over Romani centers on whether Romani discloses the claimed "aqueous extract of olives."

The Romani reference, published over a year before the filing date of the '808 Patent, discloses the polyphenolic content of five different cultivars of olive fruits from a coastal area in Tuscany. According to the article, four of the five cultivars (Rossellino, Ciliegino, Cuoricino, and Grossolana) had never before been analyzed. *See* Romani at 964, col. 2. Crucially, Romani reports that the naturally occurring weight ratio of hydroxytyrosol to tyrosol in the Rossellino cultivar is approximately 10:1, which falls within the range of weight ratios recited in claims 5 and 6 of the '808 Patent. *See id.* at Table 2. CreAgri does not dispute that Romani discloses the weight ratio recited in claims 5 and 6 of the '808 Patent. CreAgri also concedes that Romani discloses a naturally occurring weight ratio of hydroxytyrosol to oleuropein in the Rossellino cultivar of 69:1, which falls within the ranges set forth in claims 1 and 2 of the '808 Patent. Pl. Opp. at 10. Again, the Court provides a chart for simplicity.

[7] Pinnaclife also contends that Cuomo anticipates or renders obvious claim 6 of the '808 Patent. Because the Court concludes that Pinnaclife is entitled to summary judgment that Romani anticipates claim 6, it does not reach Pinnaclife's contentions as to claim 6 and Cuomo.

Claim	Limitation	Parties' Positions
All	"an aqueous extract of olives"	*Disputed*
1	"containing a weight ratio of hydroxytyrosol to oleoeuropein of between about 5:1 and about 200:1."	Disclosed by Romani (Table 2)
2	"a weight ratio of hydroxytyrosol to oleoeuropein of between about 10:1 and about 100:1."	
5	"containing a weight ratio of hydroxytyrosol to tyrosol of between about 3:1 and about 50:1."	
6	"containing a weight ratio of hydroxytyrosol to tyrosol of between about 5:1 and about 30:1."	

The Court now turns to whether Romani discloses "an aqueous extract of olives." Pinnaclife contends that, in reporting its procedure to analyze the polyphenolic compounds in the five different olive species, Romani describes an intermediate step in which the weight ratios of polyphenolic compounds claimed in the '808 Patent exist in an "aqueous solution." The Court concludes that no reasonable jury could find otherwise. In particular, Romani recounts a procedure in which the authors took olive pulps frozen in liquid nitrogen, ground them, and then used ethanol to extract the wanted polyphenols. Romani at 964, col. 2. The authors next concentrated the ethanolic extract and rinsed it with acid water to a final volume of 250 mL, forming what Romani itself calls an "aqueous solution." *Id.* Then, the aqueous solution was "defatted"—*i.e.*, the lypophillic compounds were removed—into a concentrated "aqueous phase" of 250 mL. *Id*. at 964 col. 2–965 col. 1. Both the "aqueous solution" and the defatted "aqueous phase" plainly constitute an "aqueous extract of olives" under the Court's claim construction.

CreAgri does not dispute that the expressly disclosed "aqueous solution" and "aqueous phase" compositions in Romani constitute an "aqueous extract of olives." Instead, CreAgri contends that the end result of the Romani process is not an "aqueous extract" because the authors ultimately analyzed the polyphenolic content of the olives using a "liquid-solid extraction" process that used two additional solvents—ethyl acetate and acid methanol—to create dry fractions from the aqueous solution. *See* Pl. Opp. at 9.

Taking CreAgri's description of these later steps as true, the steps nevertheless fail to create a material issue of fact as to whether the solution disclosed in Romani is an "aqueous extract of olives." Once again, CreAgri's argument disregards this Court's claim construction ruling. The Court has already concluded that the construction of "aqueous extract of olives" is not tied to any particular process, a construction that CreAgri wanted. *See* ECF No. 67 at 31–32. Accordingly, Romani's disclosure of an "aqueous solution" and "aqueous phase" is an express disclosure of the "aqueous extract" limitation regardless of whether later steps in the extraction process reduce those preparations to a solid. Romani does not suggest, and CreAgri does not contend, that the polyphenolic profiles change depending on the phase of the described olive extracts. To the contrary, Romani discloses using the dry fractions to determine the polyphenolic content of the original olive. The premise of this procedure is that the intermediate steps in the measurement process (during which the authors obtain the aqueous extract of olives) do not alter the hydroxytyrosol, tyrosol, and oleuropein levels naturally found in the Rossellino cultivar, levels that indisputably fall within the ratios stated in claims 1–2 and 56 of the '808 Patent.

CreAgri also contends that Pinnaclife's arguments with respect to Romani must meet an "'enhanced'" burden of proof because "[t]he Romani reference was already cited to the PTO during the initial prosecution of the '808 patent." Pl. Opp. at 8 (citing *Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1313 (Fed. Cir. 2011)). To the extent CreAgri is arguing that Pinnaclife's proof must be more than clear and convincing, the Federal Circuit has recently rejected that argument. *See OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 705 (Fed. Cir. 2012) ("While prior consideration of a reference during prosecution may carry some weight, the burden to prove invalidity does not change; at all times, it remains a showing 'by clear and convincing evidence.'") (quoting *Microsoft Corp.*, 131 S. Ct. at 2242). Moreover, "[w]hether the examiner actually considered this issue can only be determined by reviewing the prosecution history." *In re NTP, Inc.*, 654 F.3d 1268, 1278 (Fed. Cir. 2011). Yet there is no evidence from the prosecution history that the examiner—or anyone at the PTO—ever considered Romani during prosecution of the '808 Patent. In fact, the title page of the '808 Patent cites 22 references, including 3 that were cited by the examiner, and Romani was not among any of them. The'808

Patent specification also includes a "References" section. '808 Patent at 1:16–64. This "References" section does include Romani, as one of 24 unique references that do not appear on the '808 Patent's title page.[8] The only description of Romani in the entire '808 Patent, however, is in the specification's citation of Romani—along with 2 other articles—to describe possible "[a]dditional purification methods." *Id.* at 7:23–27. Romani is never cited in the '808 Patent's specification as containing any information on polyphenolic weight ratios. Therefore, the '808 Patent provided no indication to the examiner that Romani discloses polyphenolic weight ratios: Romani was cited in a list of 25 other "References" in the body of the specification, the '808 Patent only mentioned Romani later in the specification as being relevant for another purpose, and even there Romani was second in a string cite of three references. As a result, it is unlikely the PTO examiner ever considered Romani as a potentially invalidating reference. With the prosecution history being devoid of any mention of Romani—at least until the patent examiner in the current *Ex Parte* Reexamination found some of the '808 Patent's claims invalid as anticipated by Romani[9]—the Court simply cannot draw an inference of validity in CreAgri's favor sufficient to overcome the plain anticipating disclosure of Romani.

In sum, Pinnaclife has established the absence of an issue of material fact as to the anticipation of claims 1–2 and 5–6 of the '808 Patent by the Romani reference.

As to the claim elements added in dependent claims 3 and 4, the parties agree that Romani does not disclose these limitations. Pinnaclife makes a compelling argument that claims 3 and 4 are obvious in light of Romani in view of Cuomo, but given that the Court found above that claims 3 and 4 are anticipated by Cuomo, the Court declines to reach Pinnaclife's obviousness contention.

D. Whether the '808 Patent claims unpatentable natural phenomena under section 101

Pinnaclife has also moved for summary judgment of invalidity on the grounds that the '808 Patent claims natural phenomena and therefore is invalid under 35 U.S.C. § 101. As all claims of

[8] The '808 Patent's "References" section includes 25 total references: 24 unique references including Romani, and one other reference that also appears on the title page.

[9] Note that, as discussed in Section II.A, the Court does not rely on the PTO decision here. The Court draws its independent conclusions based on a review of the evidence in this case.

the '808 Patent are invalid under section 102 in light of either Cuomo or Romani, the Court declines to address the parties' arguments as to section 101.

IV. THE '599 PATENT

The '599 Patent claims methods of treating a broad range of inflammatory conditions using various forms of hydroxytyrosol. Pinnaclife challenges the validity of all claims of the '599 Patent on written description, enablement, and utility grounds, contending that "the specification of the '599 Patent does not support or enable the use of any hydroxytyrosol-rich composition to treat inflammation conditions claimed because the specification provides no data whatsoever to support the anti-inflammatory effects of the claimed olive-derived preparations." Def. MSJ at 19. The Court is satisfied that Pinnaclife has met its burden to show the absence of a genuine dispute as to any material issues for all three doctrines and therefore GRANTS Pinnaclife's Motion for Summary Judgment of Invalidity as to the '599 Patent.

A. The "Written Description" Requirement of Section 112

1. Applicable Law

Under 35 U.S.C. § 112(a), a patent specification must contain "a written description of the invention."[10] Under this written description requirement, the specification "must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (internal quotation marks and alterations omitted). This test requires "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art" to determine whether the specification shows that "the inventor actually invented the invention claimed." *Id.* Although "[c]ompliance with the written description requirement is a question of fact," it is, like most factual questions, "amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008).

[10] The passage of the AIA did not materially affect the written description, utility, or enablement requirements. The AIA redesignated the provisions of section 112, such that what was previously designated the first paragraph of section 112 is now designated section 112(a). *See* AIA § 4(c). For convenience, the Court refers to the redesignated provision of section 112.

2. Analysis of the '599 Patent

The Court now looks to the '599 Patent and the parties' submissions to determine if Pinnaclife has demonstrated that no reasonable fact finder could conclude that the specification supports the claimed invention. Pinnaclife argues that the '599 Patent includes no data supporting the use of hydroxytyrosol and oleuropein, either in the ratios recited in independent claim 1 and its dependent claims or in the "substantially purified" mixture recited in independent claim 16, to treat the inflammatory conditions set forth in the claims. Def. MSJ at 22.

The "level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad*, 598 F.3d at 1351 (citing *Capon v. Eshhar*, 418 F.3d 1349, 1357–58 (Fed. Cir. 2005)). In this case, the claims have a chemical nature. "[T]he chemical arts have long been acknowledged to be unpredictable," *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1370 (Fed. Cir. 2011) (Gajarsa, J., concurring) (internal quotation marks omitted); *see Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987), and patents in that field—including patents directed to treating inflammation—are often found to lack a sufficient written description, *see, e.g.*, *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004). In addition, the scope of the two independent claims in the '599 Patent is broad.[11] Broad claim scope requires more supporting detail because the recitation in the specification must "demonstrate that the inventor possesses the full scope of the invention." *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005).

Each independent claim asserts a therapy effective against several different ailments. Claim 1 recites a method of treating three conditions: coronary inflammation, bronchial inflammation, and neuro inflammation. Claim 16 recites a method of treating seven specified inflammatory conditions: "delayed type hypersensitivity reaction, psoriasis, an autoimmune disease, organ transplant, pain, fever, and tissue graft rejection." '599 Patent at 20:49–51. The claimed range of

[11] All the dependent claims of the '599 Patent (claims 2-15) depend from claim 1. *See* '599 Patent 20:6–41. The dependent claims do not limit the claimed scope of the therapeutic effect of claim 1, and CreAgri does not argue that any dependent claims are adequately described notwithstanding the status of claim 1. Accordingly, the fate of claim 1 will dictate whether the dependent claims survive summary judgment on written description grounds.

dosage levels is also broad. Both independent claims recite a dosage level for each respective ailment ranging from about 0.1 mg/kg body weight to 2000 mg/kg body weight, meaning that, for an average male of approximately 80 kg, the claimed treatment is effective for all conditions at a daily dosage level anywhere from 8 mg to 160,000 mg. Various dependent claims narrow that daily dosage to between about 0.3 mg/kg and 1 mg/kg (claim 10) and about 0.6 mg/kg (claim 11).

a. The specification fails to show that Dr. Crea possessed the full scope of the invention

A person of ordinary skill in the art would be unable to conclude from the specification that the inventor of the '599 Patent possessed the claimed invention.[12] Although the specification does describe the compositions used by the claimed methods in some detail—including how to obtain them from olive vegetation water—the specification repeatedly disclaims the novelty of obtaining the compositions themselves. *See*, *e.g.*, *id.* at 5:54–55 ("The olive-derived phenolic compounds employed herein can be prepared by a number of methods known in the art."). Instead, the specification conclusively reveals that the inventor sought to claim a method of treating inflammation based on no more than a hope that olive-derived compositions would one day be used effectively to treat inflammation caused by a wide variety of factors. As the inventor himself conceded during his deposition, this patent was filed with the anticipation that the compositions could be used as claimed, but without data showing as much. *See* Marshall Decl. Ex. C at 174:7–23 ("Crea Dep."), ECF No. 161-3 ("A: I learned early in my career that you can file patents, they are

[12] The parties disagree as to the level of ordinary skill in the art. CreAgri's expert, Dr. German, expresses his preference for a relatively low level of skill, finding one having ordinary skill in the art to be "someone with a bachelor's degree or higher in Food Science or related Biological fields related to diet and health and/or several years of experience in the life sciences research industry." German Decl. ¶ 28. In contrast, Pinnaclife's expert, Dr. Visioli, asserts that one with ordinary skill in the art has "a Ph.D. in the biological sciences, including biology, chemistry, biochemistry, biotechnology, nutritional biology, food science, or a similar field, and at least 2 years of experience studying phenolic compounds of olives and the health effects of the Mediterranean diet." Visioli Rep. ¶ 15. Without taking a position on the issue, the Court assumes for the purposes of Pinnaclife's Motion for Summary Judgment of Invalidity that CreAgri's proposed lower level of ordinary skill in the art applies. Because the specification provides no data—or even a study design—as to most of the claimed treatments, the Court's analysis on written description does not turn on the parties' debate over the level of ordinary skill in the art. Therefore, the Court finds all claims of the '599 Patent invalid despite using CreAgri's proposed lower level of ordinary skill in the art.

prophetic. . . . Q: You anticipate that this would work? A: Right. Q: But you don't actually have the data yet showing that it would work? A: Yeah. . . . .").

. The prophetic approach to patenting is not proper absent some indication that the named inventor has "actually perform[ed] the difficult work of 'invention'—that is, [he has] conceive[d] of and complete[d] the final invention." *Ariad*, 598 F.3d at 1351. A description that amounts "to no more than a 'wish' or 'plan' for obtaining [the claimed invention]" fails the written description requirement. *Id.* at 1350 (citing *Fiers v. Revel*, 984 F.2d 1164, 1170–71 (Fed. Cir. 1993)). Indeed, very little of the '599 Patent's specification is directed to treating inflammation using olive-derived phenols at all. Only about two-and-a-half columns of the nineteen-column specification discusses inflammation. *See* '599 Patent, 12:30–14:62 (subsection E, entitled "Treatment of Inflammation or Inflammation-Associated Conditions"). Although the claims are directed to methods of treating inflammations of various causes, the primary aspect discussed in the specification is "a method of treating an AIDS-associated *neurological* disorder," *id.* at 5:31–32 (emphasis added), and "[a]dditional *neurological* diseases and disturbances contemplated for treatment by the method of the invention," *id.* at 10:23–24 (emphasis added). *See also id.* at 2:33–36 ("[I]t is an object of the invention to provide, in one aspect, a method of treating an AIDS-associated neurological disorder in a subject in need of such treatment."); 8:1–63 (discussing HIV-1 Associated Dimentia); *id.* at 8:64–9:12 (HIV-Associated Myelopathy); 9:13–9:46 (peripheral neuropathy, "a very common and disabling problem encountered in HIV infection."); 9:47–10:6 (Cytomegalovirus, "a frequent secondary viral infection in AIDS patients"); 10:7–21 (Progressive Multifocal Leukoencephalopathy, "a lethal secondary viral infection mostly occurring in AIDS patients with advanced immunodeficiency"); *see also id.* at 11:44–12:29 (methods of biological testing AIDS-associated neurological disorders).[13]

[13] The '599 Patent suggests that olive-derived phenols can also treat "Alzheimer's disease; Parkinson's disease; motor neuron diseases such as amyotrophic lateral sclerosis (ALS), Huntington's disease and syringomyelia; ataxias, dementias; chorea; dystonia; dyslinesia; encephalomyelopathy; parenchymatous cerebellar degeneration; Kennedy disease; Down syndrome; progressive supernuclear palsy; DRPLA, stroke or ischemic injuries; thoracic outlet syndrome, trauma; electrical brain injuries; decompression brain injuries; multiple sclerosis; epilepsy; concussive or penetrating injuries of the brain or spinal cord; brain injuries due to exposure of military hazards such as blast over-pressure, ionizing radiation, and genetic neurological conditions." 10:23–38.

Even the subsection in the specification discussing inflammation does not explain why the inventor believed that olive-derived compositions were likely to treat any (much less all) the claimed conditions. Instead, that subsection largely discusses inflammation and its various causes generically and abstractly. *See id.* at 12:42–46 ("Typically, inflammation is a very localized response that serves to expulse, attenuate by dilution, and isolate the damaging agent and injured tissue. The body's response becomes an agent of disease when it results in inappropriate injury to host tissues . . . ."). The specification acknowledges in this section that the "composition of this invention depends on a variety of factors" and thus "the route and frequency of administration, and the particular compound employed . . . may vary widely." *Id.* at 14:26–32. Yet at no point does the specification explain why the inventor believed that the hydroxytyrosol and oleuropein compositions recited in the claims would counteract any of the listed causes of inflammation. The closest the specification comes to describing the method of treatment recited in the claims is a near verbatim (and conclusory) reproduction of the claim language itself. *See id.* at 13:10–43 ("The method [of the present invention] includes administering to the subject a pharmaceutically effective amount of substantially purified hydroxytyrosol or a substantially purified mixture of hydroxytyrosol and oleuropein."); 14:33–37 ("The pharmaceutical compositions may contain active ingredient in the range of about 0.1 to 2000 mg/kg body weight, preferably in the range of about 0.3 to 50 mg/kg and most preferably about 0.6 mg/kg."). But "generic claim language appearing *in ipsis verbis* in the original specification does not satisfy the written description requirement if it fails to support the scope of the genus claimed." *Ariad*, 598 F.3d at 1350. Here, neither the claims nor the specification discloses that the inventor possessed a treatment for inflammation caused by any of the claimed conditions, much less all of them.

b. The specification's examples fail to support the claimed invention

In contending that the specification adequately supports the claimed invention, CreAgri points to five studies described in the specification. Pl. Opp. at 19 (citing '599 Patent, 16:21–19:24). Pinnaclife responds that these studies are bare research proposals that cannot demonstrate that Dr. Crea possessed the invention. CreAgri primarily relies on these studies as prophetic; the specification reports only limited "[i]nitial results" for one of the five proposals. '599 Patent,

18:36–38. "Prophetic examples are routinely used in the chemical arts, and they certainly can be sufficient to satisfy the written description requirement." *Ariad*, 598 F.3d at 1357. A disclosure is insufficient, however, when it "is not so much an 'example' as it is a mere mention of a desired outcome." *Id*. The Court finds that the studies outlined in the specification are mere mentions of a desired outcome rather than permissible prophetic examples, and thus, the specification's examples fail to support the claimed invention.

The first study—by far the most robustly outlined study in the patent—is described in three separate "Examples." *See* '599 Patent, 16:40–18:38. These examples outline study procedures, data analysis procedures, and subject selection procedures, respectively, for a "pilot safety and tolerability" study of "the active ingredient"[14] in HIV-positive men and women "with signs and symptoms of HIV-associated cognitive-motor syndrome or frank [AIDS dementia complex]." *Id*. at 16:45–18:38. The specification discloses that "initial results" from this study "showed a statistically significant favorable change in 8-isoprostane levels in the urine." *Id.* at 18:36–38. Beyond this statement, the '599 Patent provides no results, either realized or predicted.

This study provides insufficient support for the full scope of the claimed method of treating inflammation. The study is directed to the AIDS-related neurological treatment discussed in the specification, not the treatment of the various causes of inflammation recited in the claims. *See, e.g.*, *id.* at 16:45–47 (proposing participants who suffer from "HIV-associated cognitive dysfunction"); *id.* at 11:59–63 (describing Example 1 as using an "exemplary *neuropsychological* test" (emphasis added)). Moreover, the limited finding regarding a change in 8-isoprostane levels in the urine has little relevance to the full scope of the claimed therapy. Independent claim 1 uses isoprostane found in cerebrospinal fluid ("CSF") as a marker for the purposes of administering the therapy, whereas the study measures isoprostane in the urine, without explaining how the two are related. Assuming for purposes of this motion that a person of ordinary skill in the art would understand the two isoprostane levels to be sufficiently related, the study's small dataset as to

[14] The example specifies the active ingredient to be "20 mg total phenols" but does not refer explicitly to hydroxytyrosol or oleuropein, the two substances named in the independent claims. '599 Patent at 16:46. The Court assumes for purposes of Pinnaclife's summary judgment motion that a person of ordinary skill in the art would understand the examples to refer to the compositions recited in the claims.

isoprostane levels does not support the effectiveness of the patented therapy as to the full scope of the claims (including the other two ailments recited in claim 1 and the other six claimed in claim 16). Acknowledging the small sample size ("up to 32 subjects"), the specification itself states that this study is to be used only as "a pilot safety and tolerability study" and that "statistical significance is not expected for the primary efficacy endpoint in this small study." *Id.* at 18:8–13. The '599 Patent's own predicted result, therefore, is that the study will not serve to demonstrate the efficacy of the therapy, and the Court will not read the study's abbreviated findings as more persuasive than the patentee believed possible.

Example 4 of the '599 Patent briefly sets out the remaining four studies, outlining the basic procedures for three human models and one mouse model for testing the effectiveness of an "active agent"[15] with regard to arthritis. *Id.* at 18:44–19:17. Again, these proposed studies cannot describe the full scope of the claims, as arthritis is only relevant to two of the claimed seven ailments in claim 16 and none of the three in claim 1. Moreover, these study designs fail to disclose any results whatsoever, whether realized or predicted. *See id*. The '599 Patent outlines the experiments in one or two short paragraphs of description each; this "example" reads like an internal draft study proposal, not a written description of the invention for the public. *See id.* at 18:44–48 ("Test a group of individuals with Rheumatoid Arthritis and a group with Osteoarthritis with the stress reactivity protocol, before and after 4 weeks of active agent (20 mg total phenols) supplementation and compare to controls over the same time period with no supplementation."); *id.* at 18:51–54 ("Test individuals with Rheumatoid Arthritis, before and after 10 weeks of active agent supplementation and compare to a group doing water aerobic exercise and a control group that does no intervention."); *id.* at 18:58–59 ("Test individuals with Rheumatoid Arthritis, with and without active agent supplementation for four weeks . . . ."); *id.* at 18:63–65 ("Evaluate increasing concentrations of active agent in a collagent-induced arthritis mouse model at 1.3 mg, 13 mg and 130 mg/mouse; with and without Cox-2 inhibitors."). These study proposals in fact demonstrate

[15] As discussed in note 8, *supra*, the specification defines "active agent" as "20 mg total phenols." '599 Patent at 18:46; *see also id.* at 18:52, 18:58, 18:63 (referencing "active agent" in model description).

that the inventor had not yet done the difficult work of inventing the claimed therapy. They do nothing to demonstrate that the inventor possessed the invention.

c. The '599 Patent does not inherently disclose a sufficient description of the claimed invention to a person of ordinary skill in the art

CreAgri also contends that the '599 Patent inherently satisfies the written description requirement because "the general principle that olive phenols, such as hydroxytyrosol, had anti-inflammatory properties was known by others in the art." Pl. Opp. at 19. In support of this statement, CreAgri directs the Court to its expert's declaration and five prior art references cited in the '599 Patent. Considering each in turn, the Court finds that none of this evidence raises a triable issue of fact.

Although a patentee may satisfy the written description requirement by an inherent disclosure, "'the missing descriptive matter must necessarily be present in the application's specification such that one skilled in the art would recognize such a disclosure.'" *PowerOasis*, 522 F.3d at 1306 (quoting *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998)) (alteration omitted). In other words, the written description requirement "is 'not a question of whether one skilled in the art *might* be able to construct the patentee's [invention] from the teachings of the disclosure . . . . Rather, it is a question whether the application necessarily discloses that particular [invention].'" *Id.* (quoting *Martin v. Mayer*, 823 F.2d 500, 505 (Fed. Cir. 1987) (emphasis in original); *see id.* at 1306–07 ("[T]hat the [claim element] may be obvious from the disclosure is not enough[.]") (citing *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118–20 (Fed. Cir. 2001)).

CreAgri cites Dr. German's declaration, which states that "it is inherent in the description of the patent and the appropriate markers to be measured that these be applied to a susceptible population using markers that were well understood by persons of skill in the art." German Decl. ¶ 95. Dr. German does not cite to the specification for this proposition, but presumably he refers to the paragraph in the specification that lists the relevant biomarkers. *See* '599 Patent at 13:30–42 ("The marker or the clinical symptom may include any number of markers or clinical symptoms which are generally known in the art to be associated with inflammation. Preferably, the symptoms

and markers are associated with specific types of inflammation. These include (i) the symptoms and markers in joint pain and swelling in the case of joint inflammation; (ii) elevated levels of C-reactive protein in the case of coronary inflammation; (iii) respiratory distress in the case of bronchial inflammation; and (iv) elevated CSF levels of isoprostanes or functional or psychofunctional indicators in the case of neuro-inflammation. The marker may be a cytokine, such as TNF-α, interleukin-1, interleukin-6, and/or interleukin-8. Other markers include corticotrophin, cortisol and/or prolactin."). Because the '599 Patent's specification at most discloses how to measure whether the claimed treatment works, not whether the claimed treatment in fact works, the Court finds that the '599 Patent's disclosure of the relevant biomarkers is insufficient to create an inherent disclosure of the full scope of the claimed invention.

Crucially, CreAgri's expert does not opine that the '599 Patent inherently discloses the claimed method of treatment. To the contrary, Dr. German acknowledges in the same paragraph on which CreAgri relies that inflammation is a "complex and diverse process[]." German Decl. ¶ 95. Dr. German goes on to explain that "[t]he patent discloses reasonable and appropriate biomarkers." *Id*. These biomarkers, according to the specification, are used to detect whether an individual may have an inflammatory condition. '599 Patent at 13:17–20. And claim 1, for example, uses these same biomarkers to determine whether the claimed treatment has achieved its therapeutic effect. But CreAgri never points to anywhere in the specification showing that the claimed treatment does have its therapeutic effect. Thus, at most, Dr. German's declaration states that the '599 Patent inherently discloses how to measure *whether* the treatment works as claimed, not that the treatment *does* work as claimed. That statement fails to create an issue of material fact as to whether the specification actually or inherently discloses that the inventor possessed the claimed invention.

In addition, CreAgri attempts to create an issue of fact by pointing to the '599 Patent specification's incorporation of five prior art references that discuss hydroxytyrosol's anti-inflammatory effect. None of those references, however, demonstrate the medical efficacy of hydroxytyrosol, hydroxytyrosol together with oleuropein, or olive plant extract having a given ratio of hydroxytyrosol to oleuropein, for treating inflammation arising out of the numerous causes recited in the claims of the '599 Patent. The Court addresses each of the references in turn.

- The Fehri reference, *see* Lee Decl. Vol. 2, Ex. 14, ECF No. 118-5, reported tests of the anti-inflammatory effects of olive leaf extract in mice but without reference to hydroxytyrosol or oleuropein. Moreover, the article concludes that the observed anti-inflammatory effect "could be investigated" in therapeutics, not that olive leaf extract has a therapeutic use.
- The Ragione reference, *see* Lee Decl. Vol. 3, Ex. 15, ECF No. 118-6, reported tests of hydroxtyrosol for apoptogenic activity and, although it found success with respect to a leukemia-based cell line, the article concluded that two colon cell lines, in contrast, "were completely resistant to the apoptogenic capability of DPE" and therefore "the programmed cell death due to the olive oil phenol is specific for cell phenotype," *id.* at 735–36. In other words, the article was unable to draw a conclusion about the general anti-inflammatory effect of hydroxytyrosol, much less hydroxytyrosol's anti-inflammatory effect on the various ailments recited in the claims of the '599 Patent.
- The Visioli reference, authored by Pinnaclife's expert, *see* Marshall Decl. Ex. D, reported tests of olive mill wastewater extract but made only the following conclusion:

> OMWW [olive mill wastewater] extracts *could* . . . decrease the production of pro-inflammatory factors. Additional studies are needed to verify if such anti-inflammatory effects could also take place in vivo and the exact enzymatic target of the bioactive compounds. . . . . OMWW are rich in antioxidant compounds that could be . . . employed . . . , following appropriate trials to evaluate their safety and efficacy, as prophylactic agents in the prevention of certain radical-induced human diseases.

Id. at 3401 (emphasis added). Thus, like the '599 Patent itself, the Visioli reference is, at best, prophetic only.

- The Kohyama and Petroni references, *see* Marshall Decl. Vol. 3, Exs. L–M, ECF No. 103-4, provided *in vitro* results suggesting that enzymes involved in inflammatory processes could be inhibited by hydroxytyrosol, but both also stressed the need for *in vivo* testing. *Id.* Ex. L at 350; *Id.* Ex. M at 158–59.

These references all reflect a field actively exploring the possibility of the anti-inflammatory use of hydroxytyrosol and oleuropein, as well as substances known to contain

hydroxytyrosol and oleuropein, but not at the point of inherently appreciating the use of these substances to treat coronary, bronchial, and neuro inflammation (claim 1) or inflammation caused by delayed type hypersensitivity reaction, psoriasis, and autoimmune disease, organ transplant, pain, fever, and tissue graft rejection (claim 16).

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In sum, the cited prior art does not suggest that persons having ordinary skill in the art would understand the specification's disclosure to describe that the inventor invented what was claimed. The study outlines disclosed in the specification itself all reveal that the inventor's statements of invention are, at best, premature. The written description requirement prohibits inventors from "'prempt[ing] the future before it has arrived,'" *Billups-Rothenberg, Inc. v. Associated Regional & University Pathologists, Inc.*, 642 F.3d 1031, 1036 (Fed. Cir. 2011) (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)), yet here the inventor left "[t]he actual inventive work" of generating the claimed treatment "for subsequent inventors to complete," *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1353 (Fed. Cir. 2011). Accordingly, the claims of the '599 Patent are invalid for failure to meet the written description requirement of section 112.

B. The "Enable . . . To Use" Requirement of Section 112(a)

1. Applicable Law

As the *en banc* Federal Circuit has noted, "written description and enablement often rise and fall together." *Ariad*, 598 F.3d at 1352. "In order to satisfy the enablement requirement of section 112, an applicant must describe the manner of making and using the invention 'in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same . . . .'" *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1322 (Fed. Cir. 2005) (quoting 35 U.S.C. § 112). "The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention." *In re Ziegler*, 992 F.2d 1197, 1200 (Fed. Cir. 1993). Thus, "[i]f a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to

meet the how-to-use aspect of the [section 112] enablement requirement." *In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1324 (Fed. Cir. 2009) (emphasis omitted).

Because "[e]nablement, or utility, is determined as of the application filing date," *In re Brana*, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995), an invention will not be considered useful for the purposes of section 101 where, at the time of filing, "there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention"—even if the invention is later proven useful or operable. *Rasmusson*, 413 F.3d at 1323 (quotations omitted); *see also Brenner v. Manson*, 383 U.S. 519, 535 (1966) ("Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing.").

Furthermore, "[i]f mere plausibility were the test for [enabling disclosures of utility] under section 112, applicants could obtain patent rights to 'inventions' consisting of little more than respectable guesses as to the likelihood of their success." *Rasmusson*, 413 F.3d at 1325. But the Patent Act does not provide for the patenting of mere research proposals or hypotheses. *In re '318 Patent Infringement Litig.*, 583 F.3d at 1324. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner*, 383 U.S. at 536.

"In the context of determining whether sufficient utility as a drug, medicant, and the like in human therapy has been alleged, it is proper . . . to ask for substantiating evidence unless one with ordinary skill in the art would accept the allegations as obviously correct." *Rasmusson*, 413 F.3d at 1323 (internal quotation marks omitted). In this regard, "[t]he full scope of the claimed invention must be enabled," meaning that a "patentee who chooses broad claim language must make sure the broad claims are fully enabled." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008). Regardless of the breadth of the claims, "[t]ypically, patent applications claiming new methods of treatment are supported by test results." *In re '318 Patent Infringement Litig.*, 583 F.3d at 1324. However, "testing need not be conducted by the inventor," and "human trials are not required." *Id.*

Whether a disclosure is enabling under 35 U.S.C. § 112(a) is a question of law based on underlying factual inquiries. *See Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369 (Fed. Cir. 1999). Whether an invention is operative, and hence has utility within the meaning of § 101,

appears to be one of those factual inquiries. *See In re Dash*, 118 F. App'x. 488, 490 (Fed. Cir. 2004) (citing *In re Swartz*, 232 F.3d 862, 863 (Fed. Cir. 2000)).

2. Analysis of the '599 Patent

A patent is deemed useful where "one skilled in the art would accept without question statements as to the effect of the claimed drug products." *Rasmusson*, 413 F.3d at 1323 (alternations and internal quotation marks omitted). Alternatively, there must be some quantum of data or reasoning that supports the inventor's contention that a therapy operates as claimed. *See In re '318 Patent Infringement Litig.*, 583 F.3d at 1326. The Court will consider each of these alternatives with respect to the '599 Patent.

a. One skilled in the art would not, at the time of filing, accept without question the '599 Patent's bare assertion of the claimed treatments' effectiveness

Pinnaclife argues that one having ordinary skill in the art would not accept an assertion that hydroxytyrosol and oleuropein have therapeutic anti-inflammatory qualities. The Court agrees. On this point, Pinnaclife's expert, Dr. Francesco Visioli,[16] provides clear and uncontroverted evidence: "[b]y 2002, no researcher working in the field of olive-derived polyphenols had published reliable data establishing that either hydroxytyrosol or oleuropein showed *in vivo* anti-inflammatory activity."[17] Marshall Decl. Ex. N. ("Visioli Rep.") ¶ 33, ECF No. 103-5. "[I]n the 1999-2002 time period, anti-inflammatory activity could not be inferred from research showing that olive-derived polyphenols exhibit antioxidant activity." *Id.* ¶ 34. That is, Dr. Visioli contends that the compounds in question were not known at the time of filing to provide the alleged therapeutic effects and their known antioxidant properties were not grounds for inferring such therapeutic effects.

[16] CreAgri has separately moved to disqualify Dr. Visioli based on a purported conflict of interest. *See* ECF No. 80. The Court will issue a separate order concluding that CreAgri has failed to show that Dr. Visioli should be disqualified from assisting Pinnaclife in this case.

[17] "*In vivo*" activity refers to activity "within living organisms," whereas "*in vitro*" activity refers to activity in "artificial environments outside living organisms (such as in a test tube or culture media)." *In re '318 Patent Infringement Litig.*, 583 F.3d at 1324 n.7.

CreAgri's expert, Dr. German, protests that he is "unable to determine the evidentiary basis" of the second of these two opinions. German Decl. ¶ 55. But Dr. German does not reject or otherwise controvert either of Dr. Visioli's opinions that the therapeutic effect of olive-derived polyphenols had not been established in the art. *See id.* Instead, he cites two articles written by Dr. Visioli that Dr. German contends "assert that antioxidant activity was *related* to anti-inflammatory activity in 2001 and 2002." German Decl. ¶ 55 (emphasis added). CreAgri has not provided a copy of these articles to the Court, and Dr. German's description of them fails to create an issue of fact as to whether a person of ordinary skill in the art would accept the claimed therapeutic effect of olive-derived phenolic compounds, in humans or other animals.

To avoid any doubt, the Court independently obtained and examined the two articles authored by Dr. Visioli and cited by Dr. German, and has discovered that neither establishes a recognition in the art of the therapeutic effects of olive-derived polyphenols.

The first article, "Antiatherogenic Components of Olive Oil," summarizes in three pages other studies. Francesco Visioli and Claudio Galli, *Antiatherogenic Components of Olive Oil*, Current Atherosclerosis Rep., Jan. 2001, at 64–67. The article expresses hope that phenolic compounds in olives could have therapeutic effects, but it provides no evidence whatsoever of those effects.

The second article, entitled "Antioxidant and Other Biological Activities of Phenols from Olives and Olive Oil," supplies new and successful experimental results, but its ultimate conclusion runs against CreAgri's position that a person of ordinary skill in the art would accept the claimed therapeutic effect of the claimed treatment methods. Francesco Visioli, et al., *Antioxidant and Other Biological Activities of Phenols from Olives and Olive Oil*, Med. Res. Rev., Jan. 2002, at 65–75. The article summarizes that "[t]o date, these data represent the first, albeit limited, experimental evidence of a healthful effect of olive oil components on human health. In the future, availability of pure—or even labeled—compounds in adequate quantities and development of appropriate methodologies will further clarify the metabolic fate of phenolic micronutrients, including those of olive oil." *Id*. at 71.

These statements, albeit hopeful that later research will prove a link between phenols in olives and better health, demonstrate that the link was not accepted in the art at the time of the '599 Patent's filing. Instead, this article represents some of the first steps of investigating which elements of the Mediterranean diet produce beneficial health effects. The article concludes that "[i]t is in fact difficult to single out an individual component of [the Mediterranean] diet and correlate it with the observed lower incidence of CHD [coronary heart disease] and certain cancers." *Id*. at 72. Therefore, not only are Dr. German's assertions insufficient to create a fact issue, but the articles he cites do not support the notion that a person of ordinary skill in the art would accept without question that the claimed olive-derived phenolic compounds would have the claimed therapeutic effects.

Next, CreAgri argues that one with ordinary skill in the art would nevertheless have "knowledge of the *possible* anti-inflammatory effects of olive polyphenols" and would therefore "recognize the significant benefit of the claimed inventions." Pl. Opp. at 22 (emphasis added). The undisputed record does show that, prior to the time of filing, some amount of investigation had been performed into the possible anti-inflammatory effects of olive mill wastewater and of olive-derived phenols. In particular, CreAgri points to five scientific articles cited in the patent specification as demonstrative of what was known in the art, *Id*. at 17, and Pinnaclife concedes that three of these references are reflective of research in the field, Def. MSJ at 21. These are the same references considered above in the written description section, and CreAgri reiterates the same arguments with respect to written description and enablement. The Court rejects CreAgri's arguments here as well, finding that, based on the references cited in the specification, a person of ordinary skill in the art would not accept without question the effectiveness of the claimed therapies in treating the ailments listed in the claims.

In addition, CreAgri submits post-filing articles, authored by the inventor, regarding what CreAgri claims are completed studies based on the proposals disclosed in Example 4 from the specification. *See* Lee Decl. Vol. 3, Ex. 19 ("Manuscript received 11 February 2005. . . . [A]ccepted 21 March 2005"); Ex. 20 ("Received 17 January 2007 . . . accepted 5 June 2007."). CreAgri argues that the Court should consider these results in its enablement analysis as

"pertain[ing] to the accuracy of a statement already in the specification." Pl. Opp. at 22 (quoting *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x 917, 925 (Fed. Cir. 2011)). However, the Court cannot consider CreAgri's post-filing test results as evidence of the utility of the claimed methods of treating inflammation. "Enablement is determined as of the effective filing date of the patent's application." *In re '318 Patent Infringement Litig.*, 583 F.3d at 1323. Where results "were not available at the time of the application," they cannot be used to establish utility or enablement. *Id.*, 583 F.3d at 1325; *see also* Marshall Decl. Ex. C 175 ("Crea Dep."), ECF No. 103-2 ("[T]he patent was filed while we were doing the study, and the results weren't available.").

The Federal Circuit has created a narrow exception to the rule that post-filing data cannot support utility. In *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), the Federal Circuit allowed such evidence "to substantiate any doubts as to the asserted utility" where those test results "pertain[] to the accuracy of a statement already in the specification." *Id.*, 51 F.3d at 1567 n.19. Read too broadly, however, the *Brana* exception would swallow the rule that "[e]nablement, or utility, is determined as of the application filing date." *Id.* Where actual results, garnered post-filing, mirror or otherwise substantiate predicted results, it is plain that those results will pertain to the accuracy of a statement in the specification within the meaning of *Brana*. Here, however, the '599 Patent makes no assertions whatsoever regarding the outcomes of the proposed studies, *see supra* Part III.A.2.b (discussing "Example 4" of the '599 Patent), so the study designs provided in the specification are not sufficiently prophetic such that later-achieved results can support the utility of the claimed invention. *See Brana*, 51 F.3d at 1567 n. 19 (post-filing results "do[] not render an insufficient disclosure enabling, but instead go[] to prove that the disclosure was in fact enabling when filed (i.e., demonstrated utility)").

Moreover, even if it could consider the results at issue, the Court would not conclude that the results create an issue of fact as to whether persons of ordinary skill in the art would accept without question the utility of the claimed treatment as of the filing date of the invention. The first study—a measurement in mice of a marker linked to inflammation called "tumor necrosis factor-α" ("TNF- α ")—explicitly disclaims the anti-inflammatory effects of hydroxytyrosol, both as to the mouse model in question and with regard to other, undisclosed anti-inflammatory cell models. Lee

Decl. Ex. 19 at 1478 ("HT [Hydroxytyrosol] . . . was ineffective at attenuating TNF-α production in this cell system. We evaluated the effectiveness of pure HT in other anti-inflammatory cell models and found that it was also ineffective in those models (unpublished results)."). The study concludes that "although the major phenolic compound of hydrolyzed olive water is [hydroxytyrosol], the anti-inflammatory activity [found in the study] may be attributable to another component of the water that is as yet unidentified." *Id.* Thus, CreAgri's own evidence demonstrates that the effectiveness of hydroxytyrosol as an anti-inflammatory was still uncertain to those of ordinary skill in the art even after the date of filing.

The second study measured the effect of "olive extract supplement" on male and female volunteers suffering from osteoarthritis or Rheumatoid arthritis. Lee Decl. Ex. 20 at 475. Significantly, the arthritis study did not reference relative concentrations of hydroxytyrosol to oleuropein, or, indeed, even mention either substance. *See Id*. Further, given that the study only measures the effects of the "olive extract supplement" on Rheumatoid arthritis and osteoarthritis, even a study finding that the supplement was successful in 100% of cases could not enable the full scope of the '599 Patent's claims, as the claims recite treating coronary, bronchial, and neuro inflammation (claim 1), and inflammation from psoriasis, organ transplant, fever, and tissue graft rejection (claim 16). As CreAgri highlights, this study was generally a success, finding a statistically significant reduction in several of the subjects' inflammation symptoms over the placebo group. *Id*. at 473–76. It is possible that, as to claims to an olive extract supplement treatment for Rheumatoid arthritis and osteoarthritis, this study could form the basis of an enabling disclosure. However, these are not the claims at issue. As discussed above, even if this data was available at the time the patent was filed, the arthritis study cannot enable any of the '599 Patent's claims, as it does not mention hydroxytyrosol or oleuropein. And, even if the data was available pre-filing, and even assuming that the "olive extract supplement" in the study was a supplement with the claimed ratios of hydroxytyrosol to oleuropein, the arthritis study still cannot enable the full scope of the '599 Patent's claims because it only deals with the treatment of arthritis, without mentioning any of the other claimed ailments.

In sum, Pinnaclife has satisfied its burden of establishing that no reasonable jury could conclude that a person of ordinary skill in the art would accept without question the general assertion that olive-derived phenols would effectively treat the various forms of inflammation as recited in the claims. The '599 Patent's claims are not enabled on this basis.

b. The specification and the prior art references do not otherwise establish utility

Although the operability of a patented therapy need not be demonstrated by testing in order to satisfy the utility and enablement requirements, if the claimed effect would not otherwise be accepted by one of ordinary skill in the art, there must nevertheless be some quantum of data or reasoning that supports the inventor's contention that a therapy operates as claimed. *See In re '318 Patent Infringement Litig.*, 583 F.3d at 1326. The PTO's Manual of Patent Examining Procedure ("MPEP")[18] provides that "[a]s a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a *reasonable correlation* between the activity in question and the asserted utility." MPEP § 2107.03 (emphasis added). Such a correlation may be demonstrated by "statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (*e.g.*, articles in scientific journals), or any combination thereof." *Id.*; *see also Cross v. Iizuka*, 753 F.2d 1040, 1050 (Fed. Cir. 1985) (finding a "reasonable correlation" between *in vitro* results and purported *in vivo* utility of a pharmaceutical).

As the Federal Circuit noted in *In re '318 Patent Infringement Litig.*, circumstances where analytic reasoning alone will demonstrate utility are likely to be rare, *see* 583 F.3d at 1326, and CreAgri points to no precedent in which such evidence was sufficient to satisfy utility and enablement.[19] In *In re '318 Patent Infringement Litig.*, the Federal Circuit upheld a ruling of

[18] "The MPEP . . . [is] not binding on this court, but may be given judicial notice to the extent [it does] not conflict with the statute." *In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005) (internal quotation marks omitted).

[19] CreAgri looks to *Brana* and *Actavis* to support the utility of the '599 Patent. *See* Pl. Opp. at 21–22. Neither case involved facts comparable to those at bar. In *Brana*, the Federal Circuit found that there was sufficient evidence of utility for chemical compounds intended for use as antitumor substances where the patentee disclosed *in vitro* results of the claimed compound's effectiveness and where the claimed compound was structurally similar to a compound proven to be effective *in vivo*. *See* 51 F.3d at 1563, 1567. In *Actavis*, the FDA had authorized using the compound at issue for the claimed treatment in human clinical trials, which, the court highlighted, already required the

invalidity concerning a patent for a method of treating Alzheimer's disease where the specification grounded the compound's efficacy on its other known effects as described in the scientific literature and made no reference to either *in vitro* or *in vivo* testing. *See In re '318 Patent Infringement Litig.*, 583 F.3d 1321–22. While the Court did not rule out the possibility of disclosing utility through "analytic reasoning" based on known properties, it found that any analytic insights made by the inventor were "nowhere described in the specification," and therefore did not need to reach the question of whether such insights were sufficient. *Id.* at 1326. Accordingly, although a patentee need not generally know "how or why the invention works," *In re Cortright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999) (internal quotation marks omitted), such explanations do become necessary where, as here, the inventor did not know at the time of filing whether the invention was in fact operable and instead rests the invention's asserted operability on, as the inventor himself conceded, "prophe[cy]." *See* Crea Dep. at 174:7–23.

Here, as in *In re '318 Patent Infringement Litig.*, the specification provides nothing that could be considered argument or analytic reasoning. The '599 Patent specification, at ten pages long, is at the very least more lengthy than that of the patent invalidated by *In re '318 Patent Infringement Litig*. *See In re '318 Patent Infringement Litig.*, 583 F.3d at 1321 ("The specification . . . was only just over one page in length"). It is not, however, any more revealing as to the claimed therapy. Although the specification presents various means of *testing* whether the claimed invention would work as to a small subset of the recited causes of inflammation, *see* '599 Patent at cols. 10–13, 16–19, it does not explicitly provide any analytic reasoning as to why the invention would work as claimed.

The '599 Patent does not claim a therapy, it claims a research hypothesis. "[R]esearch hypotheses do not qualify for patent protection." *Ariad*, 598 F.3d at 1353. Because a reasonable

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applicant to "provide a convincing rationale to those especially skilled in the art (*e.g.*, the [FDA]) that the investigation may be successful." 435 F. App'x at 924 (internal quotation marks omitted). Moreover, the compound at issue in *Actavis* was known to have the same relevant biological activity exhibited by another drug used to treat the same condition named in the patent, even though the other drug's safety was questioned. *Id.* at 920, 926. Here, CreAgri has not disclosed *in vivo* "evidence of success in structurally similar compounds," *Brana*, 51 F.3d at 1567, or any suggestion that the FDA has approved human trials of the claimed or similar substances.

jury could not conclude that a person of ordinary skill in the art reading the patent at the time of filing would recognize the utility of the full scope of the claimed therapies, the claims are not enabled and are therefore invalid pursuant to sections 101 and 112. The Court therefore grants Pinnaclife's Motion for Summary Judgment on invalidity as to the '599 Patent.

C. Whether the '599 Patent is invalid as indefinite under 35 U.S.C. § 112(b)

Pinnaclife has also moved for summary judgment of invalidity on the grounds that the '599 Patent is invalid as indefinite under 35 U.S.C. § 112(b). As all claims of the '599 Patent are invalid for failure to meet the written description and enablement requirements of subsection 112(a), the Court declines to address the parties' arguments as to indefiniteness.

V. CONCLUSION

For the foregoing reasons, the Court GRANTS Pinnaclife's Motion for Summary Judgment of Invalidity in its entirety. Because CreAgri asserts no patents beyond those the Court now rules invalid, the Court DENIES as moot CreAgri's Motion for Summary Judgment of Infringement. Moreover, as CreAgri's only causes of action seek to enforce patents the Court now rules invalid in their entirety, the case is hereby DISMISSED. Accordingly, the Court dismisses Pinnaclife's first Counterclaim for a Declaratory Judgment of Noninfringement of the '808 and '599 Patents and second Counterclaim for a Declaratory Judgment of Unenforceability of the '808 Patent without prejudice.[20] All other outstanding motions besides the administrative motions to seal and the motion to disqualify Dr. Visioli are DENIED as moot.[21]

[20] The Federal Circuit has held that a summary judgment grant of noninfringement does not moot a counterclaim for invalidity. *Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1370 (Fed. Cir. 2004). The Federal Circuit has held similarly with respect to a counterclaim for unenforceability. *Zenith Elects. Corp. v. PDI Commc'n Sys., Inc.*, 522 F.3d 1348, 1366–67 (Fed. Cir. 2008). Rather than moot the claim, the Federal Circuit has instructed district courts to either hear the claim or dismiss it without prejudice. *Liquid Dynamics*, 355 F.3d at 1371 ("A district court judge faced with an invalidity counterclaim challenging a patent that it concludes was not infringed may either hear the claim or dismiss it without prejudice, subject to review only for abuse of discretion."); *see also Korszun v. Pub. Techs. Multimedia, Inc.*, 96 F. App'x 699, 700 (Fed. Cir. 2004) ("(1) the district court can proceed to trial on the invalidity counterclaims and adjudicate them to finality, thus 'end[ing] the litigation on the merits and leav[ing] nothing for the court to do but execute the judgment[,];' . . . (2) the district court can dismiss the counterclaims; (3) the district court can, where proper, enter judgment under Federal Rule of Civil Procedure 54(b); and (4) the procedures of 28 U.S.C. § 1292(b), (c)(1) can be invoked." (quoting *Nystrom v. TREX Co.*, 339 F.3d 1347, 1350–51 (Fed. Cir. 2003)) (citation omitted)). Here, the Court is faced with the reverse situation of a grant of summary judgment on invalidity with outstanding counterclaims for

IT IS SO ORDERED.

Dated: December 18, 2013

LUCY H. KOH
United States District Judge

noninfringement and unenforceability. To ensure that the Federal Circuit will have proper jurisdiction for an appeal of this decision, and out of an abundance of caution, the Court dismisses the counterclaims without prejudice rather than as moot. *See Nystrom*, 339 F.3d at 1350–51 (Fed. Cir. 2003).

[21] The parties have filed various administrative motions to seal. The Court will address those motions in a separate order.